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### REMARKS

The above-listed claim amendments along with the following remarks are fully responsive to the final Office Action set forth above. This Response places the application in condition for allowance, or in better position for appeal, and entry of this Response and reconsideration of the application is requested.

The Applicants wish to thank Examiners Young and Azpuru for the telephone interview conducted November 21, 2003 with Bradley L. Christenson and Sean B. Mahoney. During the interview, claims 5-34 were discussed. The Examiner indicated that claims 5-11 would be distinguishable from the prior art of record, if claim 5 were amended to recite a coating consisting of a single thermoplastic cellulose ether. Claim 5 is accordingly amended. The Examiner further acknowledged that claims 12-26 and 31-34 are distinguishable from the art of record, without further amendment. Agreement was not reached regarding claims 27-30. Claims 27-30 are accordingly cancelled in order to expedite prosecution.

New claims 35-38 are added. After entry of this Amendment, claims 5-26 and 31-38 are pending. No new matter is introduced into the application by the claim amendment or the new claims.

The present invention, in the embodiment claimed by claims 5-11, encompasses an extended-release tablet comprising a plurality of granules consisting of potassium chloride crystals between about 20 to about 60 mesh, and a continuous coating on the crystals, the coating consisting of a single thermoplastic cellulose ether.

The invention also includes, as recited in claims 12-16, a dosage unit in tablet form comprising granules having an internal core of potassium chloride between about 20 and about 60 mesh, and a continuous external coating of ethylcellulose, wherein the granules are essentially free of surfactants or processing aids and agents.

Another embodiment of the invention, recited in claims 17-26 and new claims 37 and 38, provides fluidized-bed methods for making granules of potassium chloride coated by ethylcellulose. The methods include the step of spraying potassium chloride crystals with a mixture consisting of ethylcellulose, alcohol and water to coat the crystals.

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Also included within the scope of the invention, as recited in claims 31-34 and new claims 35 and 36, is a process to produce a pharmaceutical dosage unit in tablet form, the dosage unit comprising ethylcellulose-coated potassium chloride granules. The method includes the steps of forming a fluidized-bed of potassium chloride crystals, and spraying the potassium chloride crystals with a mixture consisting of ethylcellulose, alcohol and water to coat the crystals. A plurality of ethylcellulose-coated granules is subsequently compressed into a tablet.

#### **Claim Rejections – 35 U.S.C. § 103**

The Examiner has rejected claims 5-30 as unpatentable over U.S. Patent 4,863,743 to Hsiao *et al.* ("Hsiao"). Claims 27-30 are cancelled. With respect to claims 5-26, the rejection is respectfully traversed.

Hsiao reports a controlled-release potassium chloride tablet comprising potassium chloride crystals coated with a polymeric coating comprising ethylcellulose and either hydroxypropylcellulose or polyethylene glycol (col. 4, lines 4-21 and lines 32-33).

Claim 5 as presently amended is directed to an extended-release tablet comprising a plurality of granules consisting of potassium chloride crystals between about 20 to about 60 mesh, and a continuous coating on the crystals, the coating consisting of a single thermoplastic cellulose ether. Claims 6-11 depend directly or indirectly from claim 5, and recite additional features.

Hsiao does not make the invention recited in claim 5 obvious, for at least the reason that Hsiao does not teach or suggest a granule consisting of potassium chloride crystals between about 20 to about 60 mesh, and a continuous coating on the crystals, the coating consisting of a single thermoplastic cellulose ether. Claims 6-11 are therefore patentable over the cited reference for at least the same reason. Applicants respectfully request that the rejection be withdrawn.

Claim 12 is directed to a pharmaceutical dosage unit in tablet form comprising a plurality of granules having an internal core of potassium chloride between about 20 to about 60 mesh and a continuous external coating consisting of ethylcellulose, wherein the granules are essentially free of surfactants or processing aids and agents. Claims 13-16 depend from claim 12 and recite additional features.

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Hsiao does not make the invention recited in claim 12 obvious, for at least the reason that Hsiao neither teaches nor suggests that a coating consisting of ethylcellulose is suitable for making a controlled-release potassium chloride tablet. Claims 13-16 are patentable over the cited reference for at least the same reason. Withdrawal of the rejection is requested.

Claims 17-26 are directed to fluidized-bed processes for producing ethylcellulose-coated potassium chloride granules. The processes, as recited in independent claims 17 and 22, include the step of spraying a fluidized bed of potassium chloride crystals with a mixture consisting of ethylcellulose, alcohol and water. Claims 18-21 depend from claim 17 and recite additional features. Claims 23-26 depend from claim 22 and recite additional features.

As demonstrated in the Examples of Hsiao, potassium chloride crystals may be coated using a fluidized bed process. The process of Hsiao utilizes a co-solvent system consisting of chloroform and methanol in a 4:1 ratio (see col. 6, lines 14-16; and col. 6, lines 50-52). A mixture of polymers is dissolved in the chloroform/methanol co-solvent system. In Example 1, the mixture of polymers includes ethylcellulose and polyethylene glycol (col. 6, lines 11-13). In Example 2, the mixture of polymers includes ethylcellulose and hydroxypropylcellulose (col. 6, lines 47-52).

Claims 17-26 are not obvious in view of Hsiao, for at least the reason that Hsiao does not teach or suggest the step of spraying a fluidized bed of potassium chloride crystals with a mixture consisting of ethylcellulose, alcohol and water.

The Examiner has rejected claims 31-34 as unpatentable over U.S. Patent 4,863,743 to Hsiao *et al.* in combination with U.S. Patent 5,035,898 to Chang, *et al.* ("Chang"). The rejection is respectfully traversed.

Claims 31-34 are directed to fluidized-bed processes for producing a pharmaceutical dosage unit in tablet form, the dosage unit comprising ethylcellulose-coated potassium chloride granules. The processes, as recited in independent claim 31, includes the step of spraying a fluidized bed of potassium chloride crystals with a mixture consisting of ethylcellulose, alcohol and water. Claims 32-34 depend from claim 31 and recite additional features.

Claims 31-34 are not obvious in view of the combination of Hsiao and Chang, for at least the reason that neither Hsiao nor Chang, alone or in combination, teaches or suggests the step of

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spraying a fluidized bed of potassium chloride crystals with a mixture consisting of ethylcellulose, alcohol and water. Applicants respectfully request withdrawal of the rejection.

### Conclusion

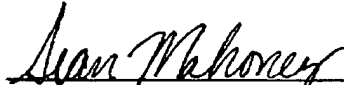
This Response places the application in condition for allowance, or in better position for appeal, and entry of this Response and reconsideration of the application is requested. All pending claims are now in condition for allowance. A notice to that effect is respectfully requested.

Should any further issues be outstanding after consideration of this Amendment, the Examiner is invited to call the undersigned at the number given below.

Respectfully Submitted,

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